

13 March 2001

CERHR  
P.O. Box 12233, MD EC-32  
Research Triangle Park, NC 27709

(Re: Public Input – Propylene Glycol (CASRN: 57-55-6))

To Whom it May Concern:

Accompanying is some rather dated (circa 1977) dissertative study material relative to the dermal pharmacology of Propylene Glycol. However, I believe there may be some important information with regards to the safety of this widely used raw material.

Three major results of the attached study were:

Propylene Glycol exhibited skin irritancy (at high enough concentrations) and did not show any evidence of being an allergic contact sensitizer.

A remarkable reduction in consumer product complaints resulted following the reduction of Propylene Glycol concentrations from 15% or greater to 9% or lower in emulsified cosmetic formulations. These reductions were most notably due to significantly lower numbers of complaints of irritation, and/or burning, stinging, itching responses on the skin.

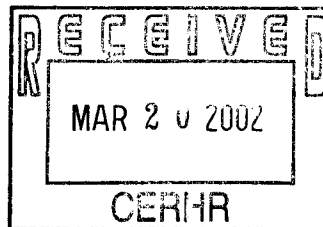
Propylene Glycol behaves in a very non-routine manner using standard dermal safety testing procedures (single and/or repeated exposure human patch tests).

Also attached is a brief outline of my qualifications and experience should you wish to consider me to serve in any capacity on or for the expert panel.

Sincerely,



Robert W. Shanahan, Ph.D.  
Vice President, Technology



**Dr. Robert Shanahan is Vice President of Technology for Consumer Product Testing Company, an independent Contract testing laboratory located in Fairfield, New Jersey, specializing in Human Clinical Studies, Analytical Chemistry, Microbiology and in vitro and in vivo Toxicology. He holds a Bachelor's degree in Biology, a Master of Science degree in Physiology and a Doctorate in Pharmacology.**

**Dr. Shanahan has been associated with the cosmetic industry, and has been involved in dermatological testing for over 30 years. He is a Life Member of the American Academy of Dermatology, a member of the American Contact Dermatitis Society, and a member of the New York Academy of Sciences. Prior to his association with dermatology, he was a research pharmacologist in the pharmaceutical industry for over ten years, involved in the development of analgesics, non-steroidal anti-inflammatories, and drugs affecting the central nervous system and gastrointestinal system.**

**Dr. Shanahan was an associate adjunct professor of Dermal Pharmacology in the Master's program at Fairleigh Dickinson University and has several publications and patents in both the pharmaceutical and cosmetic industries.**

**He was founding Manager of the Clinical Evaluation Department of Avon Products in Suffern, New York, where he spent over eleven years in pioneering, developing and improving a variety of safety and efficacy testing procedures currently in use today. He is currently an active member of the Cosmetic, Toiletry and Fragrance Association's Sunscreen Task Force and was on past task force committees involving Sunscreens, Good Clinical Practices, Hypoallergenicity, Fragrance Safety New Regulations for Clinical Investigations, and Color Additive Skin Testing.**

Consumer Product Testing Company, Inc.  
70 New Dutch Lane  
Fairfield, NJ 07004  
973-808-7111

## **CURRICULUM VITAE**

*Robert W. Shanahan, Ph.D.*

### **EXPERIENCE:**

*Vice President, Technology*  
**Consumer Product Testing Co., Inc.**  
1995 - Present

*Associate Adjunct Professor, Dermal Pharmacology*  
**Fairleigh Dickinson University, Teaneck, New Jersey**  
1987 - 1990

*Vice President and Technical Director*  
**Essex Testing Clinic, Inc., Verona, New Jersey**  
1983 - 1995

*Director of Scientific Affairs*  
**Biosphere Research Center, Inc., New City, New York**  
1980 - 1982

*Manager, Scientific Regulatory Affairs*  
**Avon Products, Inc., Suffern, New York**  
1979 - 1980

*Manager, Clinical Evaluation Department; Manager, Toxicology*  
**Avon Products, Inc., Suffern, New York**  
1969 - 1979

*Section Manager, Senior Pharmacologist, Department of Pharmacology*  
**Union Carbide Corporation, Sterling Forest Research Center, Tuxedo, New York**  
1966 - 1969

*Research Pharmacologist, Department of Pharmacology, Experimental Therapeutics  
Research Section*  
**Lederle Laboratories, Pearl River, New York**  
1959 - 1966

## **MEMBERSHIPS/ACTIVITIES**

American Academy of Dermatology (Life Member)

American Association of Pharmaceutical Scientists (AAPS)

American Contact Dermatitis Society (ACDS)

Cosmetic, Toiletry & Fragrance Association. Past task forces: Sunscreens, Good Clinical Practices, Color Additive Skin Testing, New Regulations for Clinical Investigations, Hypoallergenic Cosmetics, Fragrance Safety, currently on Sunscreen Task Force.

International Inflammation Club

New York Academy of Sciences

Rho Chi (Pharmaceutical Honor Society)

Society of Cosmetic Chemists

## **EDUCATION**

Ph.D., Pharmacology  
St. John's University, 1977

M.S., Biology/Physiology  
Fairleigh Dickinson University, 1968

B.S., (cum laude), Biology  
Fairleigh Dickinson University, 1959

## **BIBLIOGRAPHY**

Gray, W.D., Rauh, C.E., and Shanahan, R.W.: *The mechanism of the antagonistic action of Reserpine on the anticonvulsant effect of an inhibitor of carbonic anhydrase.* **Biochem. Pharmacol.** 8: 25 (1961).

Gray, W.D., Rauh, C.E., and Shanahan, R.W.: *The intracellular localization of carbonic anhydrase and a carbonic anhydrase inhibitor in the brains of mice.* **Biochem. Pharmacol.** 8(3): 307-316 (1961)

Gray, W.D., Rauh, C.E., and Shanahan, R.W.: *The mechanism of the antagonistic action of Reserpine on the anticonvulsant effect of inhibitors of carbonic anhydrase.* **J. Pharmacol. Exptl. Therap.** 139(3): 350-360 (1963).

Shanahan, R.W.: *Local activity of anti-inflammatory and irritant agents on rat paw edema induced by Carrageenin.* **Arch. int. Pharmacodyn.** 175: 186-192 (1968).

Shanahan, R.W.: *Rapid changes in the acid-base balance of the laboratory rat due to brief handling and restraint procedures.* **M.S. Thesis.** Fairleigh Dickinson University (1968).

Eloy, F.G.F., and Shanahan, R.W.: *S-triazolo-(3, 4a)-isoquinolines in treating inflammatory disorders.* U.S. Publ. Pat. Appl. B 426, 639 (July 26, 1971).

Shanahan, R.W.: *Predictability of animal models for human testing.* **CFTA Cosmet. Journ.** 3(4): 28-29 (1971).

Reimlinger, H.K., Shanahan, R.W., and Vanderwalle, J.J.M.: *S-triazolo-(3, 4a)-isoquinolines in reducing inflammation.* **U.S. Patent 3,823,238** (July 9, 1974).

Shanahan, R.W.: *An animal model for estimating the sting potential of shampoos.* **J. Soc. Cosmet. Chem.** 26: 581-592 (1975).

Eloy, F.G.F. and Shanahan, R.W.: *S-triazolo-(3, 4a)-isoquinolines in treating inflammatory disorders.* **Chem. Abstr.** 84: 470 (1976).

Shanahan, R.W.: *The dermatopharmacologic activity of propylene glycol in selected cosmetic formulations.* **Ph.D. Thesis,** St. John's University (1977).

Shanahan, R.W.: *Interpreting the results of human allergic contact sensitization testing.* Presented at the **CTFA Scientific/Regulatory Conference**, Washington, D.C. (1979) and **COSMOEXPO**, New York, New York (1980).

**BIBLIOGRAPHY (continued)**

Shanahan, R.W.: *Propylene Glycol and the Cosmetic Chemist - Important Considerations in Formulating and Safety Testing*. Presented at the N.Y. **Chapter S.C.C.**, January 1984; the **Connecticut Chapter S.C.C.**, June, 1984; and the **Mid-Atlantic Chapter S.C.C.**, March, 1985.

Shanahan, R.W., and Schwartz, H.: *Parameters for Assessing the Efficacy of Skin Care Products*. **Drug and Cosmet. Ind.** 140(1): 42-48 (Jan. 1987).

Murphy, E.J. and Shanahan, R.W.: *Manufacturer's Obligations with Regard to Safety and Efficacy Testing of Sunscreen Products Under the Final US Sunscreen Monograph*. In **Cosmetics and Toiletries Manufacture Worldwide**, pp 324-328, Aston Publ. Gp. (2000).

Shanahan, R.W., Weiss, M., Weiss, C. and Murphy, E.J.: *Consumer Testing and Evaluation of Personal Care Products*. In a revision of M. deNavarre's **The Chemistry and Manufacture of Cosmetics**, Third Ed., Vol. 1, Basic Science, Chapter 15, Allured Publishing Corp. (2000).

Shanahan, R.W.: *The Art and Science of Repeated Insult Patch Testing*. Lecture Series, presented to the Southwest Chapter S.C.C. (1999), Toronto Chapter S.C.C. (1999), Montreal Chapter S.C.C. (2000).